EXHIBIT B

(19) REPUBLIC OF FRANCE
NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY
PARIS

(11) Publication No.: **2 734 151**
(Use only for reprint requests)

(21) National registration No.: **95 05946**

(51) Int. Cl[5]: A 61 F 2/66.

(12) **PATENT APPLICATION** **A1**

(22) Application date: April 15, 1995

(30) Priority:

(43) Date application laid open to public inspection: Nov. 22, 1996 *Bulletin* 96/47.

(56) List of documents cited in preliminary search report: *See end of this document.*

(60) References to other related national documents:

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(54) REACTIVE PROSTHETIC FOOT STRUCTURE.

(57) Limb prosthesis.
- The structure is characterized in that:
- the sole plate (10) constitutes a reactive element in the form of a leaf spring having
  - an arch shank (11),
  - an anterior spatula (12) extending the arch frontward and having the reverse curve from that of the arch,
  - a posterior spatula (13) extending the arch rearward and having the reverse curve from that of the arch,
- the ankle armature (20) is comprised of a C-shaped reactive element elastically deformable in its plane connected to the sole plate in the part connecting the arch to the rear spatula.
Application to full foot prostheses.

[figure]

The present invention relates to the field of external prostheses designed to reconstitute or replace a failing natural organ, and specifically relates to the field of prosthetic feet viewed in the complete functional sense, i.e. including the ankle joint (to which for this purpose the distal epiphyses of the tibia and fibula belong).

The need to compensate for the absence of a natural foot has been felt for a number of years, and many proposals have been formulated along these lines.

The earliest proposals consisted simply of replacing the natural foot by a rigid prosthesis, made of wood for example, later fitted with a joint designed to assume the functions of the ankle.

Subsequently, more elaborate proposals were formulated to incorporate structures in the form of a leaf spring embedded in a restoring substance such as elastomer. One example of such a technique is illustrated by US Patent 4,959,073.

Whatever the materials used to make such structures, they quickly proved to have the advantage of restoring the work stored during walking, and may be termed "reactive" or "dynamic"; however, they must be made in various designs so that their reactivity characteristics can be adapted. When this is done, however, the cost of such prostheses becomes incompatible with the objectives in view when fitting a handicapped individual.

Moreover, such prostheses are believed not to have the appropriate lateral stability and raise support problems when walking is done on irregular or uneven ground. It will readily be seen that such a drawback is virtually prohibitive for a handicapped individual.

The prior art includes another proposal for a structure made from a sole plate to which is fitted a substantially U-shaped armature whose center part or web points forward. One of the branches is connected to the sole plate such that the center U-shaped part is substantially one-third from the front end of the sole plate and the second branch is designed to support the linking means with a post.

A technique of this type can be illustrated by French Patent 88-16573 (2,640,499).

In such a proposal, the U-shaped armature appears to be designed to assume a spring function favoring a certain flexibility of attack which is completed by the interposition of an elastic pad between the two branches of the armature.

While the impact of the heel can be cushioned by such means, the reactive nature which is desired, and which one is entitled to expect, does not take the various walking phases into account.

The first drawback that must be noted is the situation at the anterior third of the part of the U-shaped armature responsible for flexion. Such a position does not correspond to the push-off and return phases and natural flexion around the axes of articulation of the natural ankle.

Moreover, the reaction of the elastic pad during push-off when the heel leaves the ground tends to produce the relative spreading or opening of the upper branch of the armature and thus delays the flexion function that should normally occur by means of the sole plate to correspond to the return phase naturally effected by the relative movement between the metatarsus and the toes.

Such drawbacks do not lead to optimal comfort or to fitting the patient for normal walking and/or physical exercise or athletic activities which involve greater impacts with the ground and more rapid and extensive movements of the metatarsus.

The goal of the invention is to propose improvements to a prosthetic foot belonging in particular to the second group above such that the characteristics of flexion, cushioning the impact of the heel, reactive return of the sole, and transverse stability can be provided in order to favor normal gait and/or physical exercises involving the feet.

To achieve the above objectives, the reactive prosthetic structure is characterized in that

- the sole plate constitutes a reactive element in the form of a leaf spring having
- a substantially central arch shank,
- an anterior spatula forming a forefoot, extending the arch frontward and having the reverse curve from that of the arch,
- a posterior spatula forming a heel, extending the arch rearward and having the reverse curve from that of the arch,
- the ankle armature is comprised of a C-shaped reactive element elastically deformable in its plane and connected by one of its branches to the sole plate in the part connecting the arch to the rear spatula.

Other features will emerge from the description hereinbelow with reference to the attached drawings which show embodiments of the subject of the invention as nonlimiting examples.

Figure 1 is an elevation view of the reactive structure according to the invention.

Figure 2 is a plan view essentially along line II-II in Figure 1.

Figure 3 is a plan view similar to Figure 2 but showing a variant embodiment on a smaller scale.

Figures 1 and 2 illustrate the reactive structure of the prosthetic foot to be incorporated into a coating 1 made of any appropriate material usual in prosthesis technology. For this reason, such a coating will not be described below, being deemed to be prior art. For information, the purpose of such a coating is to represent a prosthesis defining an ankle 2, the foot itself 3 which is the closest shape possible to an ordinary foot including in particular an arch 4 provided between a rear protuberance 5 creating the heel and a forefoot 6.

The reactive structure of the prosthetic foot according to the invention comprises a sole plate 10 made in the form of a leaf spring to offer some elastic deformability. The sole plate 10 can be made of a number of different materials, but to combine the characteristics of strength, flexibility, and lightness it appears preferable to make this sole plate of carbon fibers impregnated and embedded in a polymerized resin, for example, from woven carbon fibers made in successive layers, applying the technology already in use in other areas.

The sole plate 10 is formed to present a substantially central curved part 11 forming an arch shank that is extended by two terminal parts termed anterior spatula 12 and posterior spatula 13. Preferably but not necessarily, the sole plate 10 has a constant thickness over the arch shank part and gradually decreasing thickness in the direction of spatulas 12 and 13.

The shape of sole plate 10 is also chosen such that the curve of spatula 12 is the reverse of that of arch 11; likewise that of posterior spatula 13.

Sole plate 10 is made such that, for its utilization, the face 14a corresponding to the hollow of the arch shank proceeds in the direction of an imaginary support plane such as that designated by the letter P and which, for better understanding, is considered as the

ground being walked upon. The opposite face 14b of sole plate 10 is then directed upward.

The sole plate 10 is surmounted by an ankle armature 20 made of a substantially C-shaped reactive element elastically deformable in its plane. The ankle armature is advantageously also made as stated above regarding sole plate 10. The ankle armature has two branches 21 and 22 connected by a curved web 23. The ankle armature 20 is fitted by the connecting branch 22 onto surface 14b of sole plate 10 such that it is located, by a vertically oriented imaginary reference axis x-x', at a distance from the end edge of rear spatula 13 that is between one-quarter and one-third the length of sole plate 10. In this situation, the ankle armature is oriented such that the branches 21 and 22 are directed rearward while the web 23 is directed frontward.

The connection between branch 22 and sole plate 10 is either permanent or removable, with the choice of the best solution depending essentially on the materials used and the methods of manufacture, it being understood that the articulated structure may be made in one piece such that at least part of the connecting branch 22 is blended with the corresponding part of sole plate 10.

Branch 21 has a large and constant thickness to constitute a rigid non-deformable seat on which an extension for fitting to the leg such as a post or the like can be provided in any appropriate known manner.

According to one preferred but not mandatory arrangement, the thickness of ankle armature 20 decreases gradually in the direction of the connecting branch 22 such that the center part of web 23 constitutes an elastic flexion area when subjected to a force that pushes branches 21 and 22 closer together, and a reactive area restoring the stored work when such a force is released.

The armature 20 can have a constant width or a variable width according to the desired flexion characteristics in particular, especially at the level of web 23.

In view of the shape of the sole plate and ankle armature, particularly in the arch shank area, as well as the direction in which the ankle armature is fitted, the reentrant angle delimited by the opposite faces of this armature and of the sole plate can be utilized to introduce a factor varying the flexion characteristic of web 23, for example by interposing a wedge 24 made of an appropriate elastomeric material.

According to another provision of the invention, the connecting branch 22 has, at least in its end portion, a radius of curvature r that is less than the radius of curvature R of the curve of the posterior spatula 13. This arrangement is designed to confer a flexibility characteristic both on the rear spatula 13 when it strikes the ground to cushion part of the impact energy by absorption and to provide simultaneous flexion of both spring parts concerned when the spatula 13 abuts the end portion of branch 22.

Objectively, it is advantageous or even preferable to make the branch 22 such that the end edge of its end portion is retracted from the end edge of spatula 13.

According to another design provision appearing in Figure 1, the sole plate 10 is made such that, while still adhering to the arrangements described above, the rear spatula 13 is located in a plane raised relative to plane P when the spatula 12 is resting on this plane and the upper branch 21 occupies a substantially horizontal plane P_1. Such a condition is met by shaping the arch shank 11 such as to favor the length of its part connecting with the anterior spatula 12 and providing, on the face pointing to plane P of the posterior spatula, a compensating body 25 that can be termed a "heel."

The design provisions above enable the following effects to be achieved during the various gait phases.

The impact of the heel on the ground is cushioned by the first flexion of spatula 13 which, in a second stage, causes the end portion of branch 22 to flex. The additional unabsorbed energy generated by this impact is then absorbed by the flexion of web 23, which is then completed when spatula 12 makes contact with the plane P by flexion of the arch shank 11.

During push-off, the stored work is restored by the ankle armature 20 and the arch shank 11, while generating flexion of the anterior spatula 12 to produce a push-off effect like the effect naturally produced by the metatarsal bones and the toe phalanges.

As can be seen in Figure 1, this phase is reproduced under the best conditions by the differential flexibility prevailing at the anterior spatula 12 due to the variation in its thickness, possibly combined with the spatula shape illustrated in Figure 2, but also by the angle of rise α conferred by the curve imposed on anterior spatula 12 when static.

To improve the energy restoration and flexion of the anterior spatula 12 during push-off, it is advantageous to supplement the armature 20 with a tightener 30 subtending

the arc defined by this armature. Preferably the tightener 30 is interposed between branches 21 and 22 and constitutes a non-stretchable cord held between the branches to assume a function that could be considered analogous to that of the natural Achilles tendon. The cord 30 can be made in several appropriate ways and could be connected to branches 21 and 22 by removable attaching means that however prevent any risk of relative sliding.

According to another provision of the invention, the sole plate 10, in at least one of its lengthwise edges, has a recess 40 specifically involving the arch shank. Such a recess improves the lengthwise flexion characteristics while providing a possible twisting reaction that favors absorption of level compensations when walking over sloping or uneven ground.

The example according to Figure 2 shows two recesses 40 and 41, identical in position and shape, so that part 11 assumes a torsion bar function, for example in alignment with a lengthwise median axis y-y' of the sole plate. Of course, an asymmetric design could also be used, for example the type of design illustrated in Figure 3 showing one embodiment of the sole plate for making a right prosthetic foot reactive structure, it being understood that a symmetrical embodiment for the left foot must also be considered.

The invention is not limited to the examples described and shown, as a number of modifications can be made thereto without departing from its framework.

CLAIMS

1. Reactive prosthetic foot structure of the type having a curved sole plate (10) surmounted by a C-shaped ankle armature (20) opening rearward and having two branches (21, 22) connected by a curved web (23), characterized in that

- the sole plate (10) constitutes a reactive element in the form of a leaf spring having
  - a substantially central arch shank (11),
  - an anterior spatula (12) forming a forefoot, extending the arch frontward and having the reverse curve from that of the arch,
  - a posterior spatula (13) forming a heel, extending the arch rearward and having the reverse curve from that of the arch,
- the ankle armature (20) is comprised of a C-shaped reactive element elastically deformable in its plane and connected by one of its branches to the sole plate in the part connecting the arch to the rear spatula.

2. Reactive prosthetic foot structure according to Claim 1, characterized in that the armature (20) is connected to the sole plate (10) in an area of the latter that is between one-third and one-quarter of its length starting from the transverse end of the heel.

3. Reactive prosthetic foot structure according to Claim 1 or 2, characterized in that the armature (20) has an upper branch (21) forming a sole plate for fitting a post and in that the sole plate (10) is made such that the lower face of the posterior spatula (13) is located on a horizontal plane that is raised with respect to the equally horizontal plane (P) tangental to the anterior spatula (12) when the upper branch (21) occupies an essentially horizontal plane (P_1).

4. Reactive prosthetic foot structure according to one of Claims 1 to 3, characterized in that the thickness of the armature (20) is constant at the sole plate and the thickness decreases gradually in the direction of the branch connecting to the sole plate.

5. Reactive prosthetic foot structure according to one of Claims 1 to 4, characterized in that, for connection with the sole plate, the armature (20) has a branch (22) whose end portion is curved with a radius of curvature (r) that is less than the radius of curvature (R) of the posterior spatula.

6. Reactive prosthetic foot structure according to one of Claims 1 to 5, characterized in that, for the connection with the sole plate, the armature (20) has a branch (22) whose transverse end is recessed from that of the heel.

7. Reactive prosthetic foot structure according to one of Claims 1 to 6, characterized in that the armature is connected with the sole plate with interposition of a wedge (24) made of elastomeric material occupying the reentrant angle defined by the opposite faces of the armature and the sole plate.

8. Reactive prosthetic foot structure according to one of Claims 1 to 7, characterized in that the armature (20) is completed by a tightener (30) subtending the arc defined by the armature.

9. Reactive prosthetic foot structure according to one of Claims 1 to 8, characterized in that the armature (20) is completed by a tightener comprised of a non-stretchable cord held between branches (21, 22).

10. Reactive prosthetic foot structure according to Claim 8 or 9, characterized in that the tightener (30) is fitted to the branches by removable attaching means.

11. Reactive prosthetic foot structure according to one of Claims 1 to 9, characterized in that the armature (20) has a constant width.

12. Reactive prosthetic foot structure according to Claim 1, characterized in that the sole plate has a recess (40) on at least one of its lengthwise edges and in the part corresponding ot the arch.

13. Reactive prosthetic foot structure according to Claim 1 or 12, characterized in that, in plan view, the sole plate has the apparent geometric shape of a right or a left foot.

14. Prosthetic foot including a reactive structure according to one of Claims 1 to 13.

PRELIMINARY SEARCH REPORT

DOCUMENTS DEEMED PERTINENT		Claims concerned of examined document
Category	Document listing, indicating pertinent parts where necessary	
X Y	DE-U-93 15 665 (IOPS GmbH & Co. KG) * claims; figures * * page 7, line 14 – page 9, line 7 *	1-6, 11, 7, 12, 13
X, D	FR-A-2,640,499 (Palfray) * page 3, line 22 – page 4, line 35; figures 1-4 *	1
Y	WO-A-94 10942 (Composites-Busch * page 8, line 3 – line 6; figures 2 *	7
Y	FR-A-2,698,538 (Etablissements Proteor) * abstract; figure 2 *	12, 13
A, D	US-A-4,959,073 (Merlette) * abstract *	1

Date search completed: January 25, 1996
Examiner: Sánchez y Sánchez, J.